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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,625	06/02/2000	Carlos F. Barbas III	22908-1227B	6568

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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/586,625

Applicant(s)

BARBAS ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**P r i d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-35,37-46 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-35,37-46 and 69-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal Matters***

Claims 1, 8, 13, 20, 22, 25, 32, 39, 43, 45, 69 and 73 were amended in Paper No. 15, 5/5/2003. Claims 1-3, 5-35, 37-46, 69-73 are pending and under consideration.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 5/5/2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. Applicants listing of copending Applications is acknowledged, and has also been considered.

### ***Response to Arguments and Amendment***

Applicant's arguments filed in Paper No. 15, 5/5/2003 have been fully considered but they are persuasive in part.

In Paper No. 10, 11/21/2001, Applicant elected without traverse Group I, claims 1-35, 37-46, 69-73, drawn to a fusion protein encoded by SEQ ID NO: 1. Applicant requests clarification of the restriction requirement and election of species. The requirement for the election of species is withdrawn based upon the prior art as set forth in the rejection under 35 USC § 102(b), *infra*. Independent Groups drawn to fusion proteins encoded by SEQ ID NOs: 2-18 will not be rejoined because they are independent and distinct inventions, which require non-coextensive searches, and a search of one of the sequences would not reveal art on any of the other sequences, thus imposing a burden on the Examiner.

The rejection of claims 1-3, 5-35, 37-46, 69-73 under 35 U.S.C. 112, because the specification does not enable any person skilled in the art to which it pertains, or with which it is

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most nearly connected, to make and use the invention commensurate in scope with these claims has been withdrawn.

The rejection of claims 1-3, 5-35, 37-46, 69-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn.

The rejection of claims 1-3, 5-38, 43-46, 69-73 are rejected under 35 U.S.C. 102(a) as being anticipated by Beerli et al. (1998) has been withdrawn.

The rejection of claims 1-3, 5-35, 37-46, 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerli et al. (1996) has been withdrawn.

### ***Claim Objections***

Claim 22 stands objected to because of the following informalities: It contains subject matter drawn to non-elected subject matter. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 5-35, 37-46, 69, 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheller et al. (1998).

Scheller et al. assessed the role of different receptor domains in hormone-specific response by testing chimeras of AR and GR for their ability to activate the androgen-specific enhancer of the mouse sex-limited protein (Slp) gene (page 24216, Figure 24218). The chimeric fusion proteins of Scheller et al. combine the amino terminal, DNA binding and ligand binding domains of the AR and GR in various combinations (see page 24218, Figure 1). This meets the limitations in claims 1 and 69 for a fusion protein comprising a LBD from an intracellular receptor, and a zinc finger DBD wherein the fusion protein is a ligand activated transcriptional regulator. The claims recite that the LBD is modified to change ligand specificity from the native hormone receptor. In the Scheller reference the LBD of AR and GR are changed, thus meeting this limitation. The DBD regulates transcription, thus claim 2 is anticipated. The chimeric proteins are nuclear hormone receptors, thus claim 3 is anticipated, and the chimeric proteins have altered cross reactivity compared to the original ligand, thus claim 5 is anticipated. The chimeric proteins of Scheller comprise zinc finger domains that meet the limitations regarding binding of claims 6-7. The chimeric proteins of Scheller comprise C2H2 domains in the zinc finger region of the DBD, thus claim 8 is anticipated, and the chimeric fusion protein comprises at least one zinc finger domain or variants thereof, thus claims 9, 10 and 73 are anticipated. Claims 11 and 12 are anticipated because the chimeric proteins comprise androgen and glucocorticoid receptors. Claim 13 is anticipated since there is no structural limitation on the degree by which the claimed fusion protein may vary from either the estrogen receptor or progesterone receptor, thus the AR and GR chimeras of Scheller et al. meet the limitations. The

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chimeric proteins activate transcription, thus claim 14 is anticipated, and claims 15-19 are anticipated because there is no structural limitation on the degree by which the claimed fusion protein may vary from the transcription activation domains, thus the chimeric proteins of Scheller meet these limitations. Claim 20 is anticipated because the chimeras are ligand activated transcriptional regulators, and claim 21 is anticipated because there is not structural limitation on the "derivatives" of the repression domains which the claimed fusion proteins must comprise, thus the chimeric proteins meet the limitations.

Scheller et al. set forth nucleic acids encoding the chimeric proteins (page 24217, column 1, second paragraph), thus claims 23-24, 26-31. The vectors of Scheller et al. were constructed using viral vectors (page 24217, column 1, fifth paragraph), thus claims 32-38 are anticipated. Scheller et al. teaches the transfection of cells with nucleic acids encoding chimeric receptors and hormone response elements upstream of reporter genes thus claims, 39-46 are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-35, 37-46, 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheller et al. (1998) in view of Sibson et al. (WO/9401548). The claims recite non-viral vectors and cells comprising nucleic acids encoding the fusion proteins of the invention. As taught in the above rejections under 35 USC 102, the Scheller reference teaches the claimed fusion proteins and nucleic acids. Scheller et al. does not teach non-viral vector. However,

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Sibson et al. do teach the use of non-viral vectors and cells to express DNA, as well as methods of producing proteins.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Sibson et al. by substituting a cDNA in the polycloning region of the vector with the polynucleotide (cDNA) of Scheller et al. for the purpose of transfecting a host cell as taught by Sibson et al. in view of Sibson et al.'s suggestion that it would be desirable to do so (pages 8-13). One of ordinary skill in the art would have been motivated to make this substitution in order to express the protein encoded by the introduced DNA in a host cell to perform ligand binding and functional assays. There would have been a reasonable expectation of success for a person of ordinary skill in the art to make this invention since these techniques are widely used in the art and are highly successful (Sibson et al., page 10, line 38 - page 12, line 42). The present invention, therefore, is *prima facie* obvious over the above references in the absence of evidence to the contrary.

### ***Conclusion***

No claim is allowed.

### ***Advisory Information***

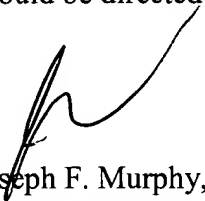
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the


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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
September 22, 2003



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